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## 5.0 510(k) SUMMARY

MAR - 5 2008

In accordance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR section 807), and in particular section 807.92, the following summary of safety and effectiveness information is provided:

### 5.1 Submitted By:

RJ Medical, Inc.
4921 Robert J. Mathews Pkwy., #2
El Dorado Hills, CA 95762
Telephone: 1(916)941-6913
Contact: Jim Innes
President
Date Prepared: December 14, 2007

### 5.2 Device Name:

| | |
|---|---|
| Trade or Proprietary Names: | PVA PLUS" Vial PVA Foam Embolization Particles |
| | PVA PLUS" Convenience Kit PVA Foam Embolization Particles |
| | MicroStat" Convenience Kit PVA Foam Embolization Particles |
| | MaxiStat" Convenience Kit PVA Foam Embolization Particles |
| Common or Usual Name: | Polyvinyl alcohol (PVA) foam embolization particles |
| Classification Name: | Vascular embolization device |

### 5.3 Predicate Devices

The subject devices are substantially equivalent to the following predicate devices:

- PVA PLUS" Foam Embolization Particles (Surgica Corp.; K001678)
- MaxiStat" PVA Foam Embolization Particles (Surgica Corp.; K020033)
- MicroStat" PVA Foam Embolization Particles (Surgica Corp.; K032619)

- Modified PVA PLUS™, Modified MaxiStat™, and Modified MicroStat™ PVA Foam Embolization Particles (Protein Polymer Technologies, Inc.; K053548)

- Modified PVA PLUS™, Modified MaxiStat™, and Modified MicroStat™ PVA Foam Embolization Particles (Protein Polymer Technologies, Inc.; K061790)

## 5.4 Device Description

The subject devices are particles of nonabsorbable synthetic polyvinyl alcohol (PVA) foam. The devices do not contain any colorant or other additive, and are uncoated. Each is offered in a range of particle sizes, from which the clinician may select the particle size most appropriate for the desired effect and targeted vasculature. The devices are intended to be delivered to the selected anatomical site by means of a syringe through an infusion catheter of appropriate diameter. The devices are provided sterile, non-pyrogenic, and are intended for single use.

## 5.5 Intended Use

PVA particles are indicated for vascular occlusion of blood vessels within the neurovascular and peripheral vascular system. They are intended for arterial embolization of arteriovenous malformations (AVMs) and hypervascular tumors in the peripheral vasculature, and for vascular occlusion of blood vessels within the neurovascular system for the embolization of AVMs and neoplastic lesions.

## 5.6 Comparison to Predicate Devices

The subject devices are identical to both the Surgica product (K001678) PVA Foam Embolization Particles and the Corporation Protein Polymer Technologies, Inc. product (K053548 & K061790) Modified PVA PLUS™, Modified MaxiStat™, and Modified MicroStat™ PVA Foam Embolization Particles. Surgica Corporation was the exclusive developer and only manufacturer of all of these products. Surgica Corporation recently sold all of the assets, including Patents, Trademarks, Fixtures, Quality Systems, Procedures, Specifications, etc. to RJ Medical. Former Surgica management has transferred everything to RJ Medical, including training, to resume manufacturing and distribution of the devices. The only changes to the products are the manufacturer and the distributor identifications. Names on the labeling will reflect these items.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RJ Medical, Inc.
% Mr. Jim Innes
President
4921 Robert J. Mathews Parkway, #2
El Dorado Hills, California 95762

MAR - 5 2008

Re: K073544
Trade/Device Name: PVA PLUS™ Vial PVA Foam Embolization Particles
PVA PLUS™ Convenience Kit PVA Foam Embolization Particles
MicroStat™ Convenience Kit PVA Foam Embolization Particles
MaxiStat™ Convenience Kit PVA Foam Embolization Particles
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: II
Product Code: KRD
Dated: February 21, 2008
Received: February 21, 2008

Dear Mr. Innes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

RJ Medical, Inc.

# Indications for Use

510(k) Number (if known): K073594

Device Names:

PVA PLUS™ Vial PVA Foam Embolization Particles
PVA PLUS™ Convenience Kit PVA Foam Embolization Particles
MicroStat™ Convenience Kit PVA Foam Embolization Particles
MaxiStat™ Convenience Kit PVA Foam Embolization Particles

Indications for Use:

PVA particles are indicated for vascular occlusion of blood vessels within the neurovascular and peripheral vascular system. They are intended for arterial embolization of arteriovenous malformations (AVMs) and hypervascular tumors in the peripheral vasculature, and for vascular occlusion of blood vessels within the neurovascular system for the embolization of AVMs and neoplastic lesions.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices



510(k) Number K073594